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APPLICATION NO. FIRST NAMED INVENTOR **FILING DATE** ATTORNEY DOCKET NO. 09/549,827 04/14/00 RZHETSKY A31869-A7005 **EXAMINER** HM12/0102 BAKER BOTTS L.L.P. ZHOU, S 30 ROCKEFELLER PLAZA ART UNIT PAPER NUMBER NEW YORK NY 10112 1631 **DATE MAILED:** 01/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | 1 | |
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| | Application No. | Applicant(s) |
| Office Action Summary | 09/549,827 | RZHETSKY ET AL. |
| | Examiner | Art Unit |
| | Shubo "Joe" Zhou | 1631 |
| The MAILING DATE of this communication appe Period for Reply | ars on the cover sheet | with the correspondence address |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. | ' IS SET TO EXPIRE 1 | MONTH(S) FROM |
| Extensions of time may be available under the provisions of 37 after SIX (6) MONTHS from the mailing date of this communi If the period for reply specified above is less than thirty (30) day be considered timely. If NO period for reply is specified above, the maximum statutory communication. Failure to reply within the set or extended period for reply will, by Status | cation. s, a reply within the statutory period will apply and will ex | y minimum of thirty (30) days will pire SIX (6) MONTHS from the mailing date of this |
| 1) Responsive to communication(s) filed on | · | |
| · _ · · · · · · · · · · · · · · · · · · | — is action is non-final. | |
| 3) Since this application is in condition for allowa closed in accordance with the practice under E | nce except for formal r | |
| Disposition of Claims | | |
| 4) Claim(s) 1-32 is/are pending in the application. | | |
| 4a) Of the above claim(s) is/are withdraw | | |
| 5) Claim(s) is/are allowed. | | |
| 6) Claim(s) is/are rejected. | | |
| 7) Claim(s) is/are objected to. | | • |
| 8)⊠ Claims <u>1-32</u> are subject to restriction and/or el | lection requirement. | |
| Application Papers | | |
| 9) The specification is objected to by the Examine | r | |
| 10) The drawing(s) filed on is/are objected to | | |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved. | | |
| 12) The oath or declaration is objected to by the Ex | | i∐ disapproved. |
| The dati of decidation is objected to by the Ex | annici. | · |
| Priority under 35 U.S.C. § 119 | | |
| 13) Acknowledgment is made of a claim for foreign | priority under 35 U.S.(| C. § 119(a)-(d). |
| a) All b) Some * c) None of the CERTIFI | ED copies of the priori | ty documents have been: |
| 1. received. | | |
| 2. received in Application No. (Series Code | : / Serial Number) | <u> </u> |
| 3. received in this National Stage application | n from the Internationa | l Bureau (PCT Rule 17.2(a)). |
| * See the attached detailed Office action for a list of | of the certified copies n | ot received. |
| 14) Acknowledgement is made of a claim for domes | stic priority under 35 U | .S.C. & 119(e). |
| Attachment(s) | | |
| 15) Notice of References Cited (PTO-892) 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) | 19) 🔲 Notice | iew Summary (PTO-413) Paper No(s)e of Informal Patent Application (PTO-152) |

U.S. Patent and Trademark Office PTO-326 (Rev. 3-98)

Art Unit: 1631

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

This application contains sequence disclosures as those on pages 27, 28 and in Figures 14A, 14C, etc. that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132. Applicant is reminded that when a sequence is presented in a drawing regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings.

Applicant is given ONE MONTH from the mailing date of this communication within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

It is noted that Applicant attempted to file a paper copy of Appendix H on a Microfiche. Microfiche is unreadable by the examiners and other users without special equipment, and requires special equipment to duplicate for sale to the public. The

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Office is encouraging the submission of the "paper copy" on CD-ROM. CD-ROMs are easy to read and to duplicate using standard Office equipment.

Applicant should submit a petition to allow a CD-ROM copy to take the place of a paper copy of Appendix H.

The Office is cognizant of the difficulty for both the applicant and its own departments in handling applications of this enormous size in the paper medium. We thus are inclined to accept submissions for very large sequences and any other very large sections of the application. However, the Office is now almost entirely paper based. To allow our Office to process on this unfamiliar medium, we must require submissions to conform to the following rules:

- 1. In lieu of providing a paper Sequence Listing for the subject application as required by 37 C.F.R. § 1.821 *et seq.* or any other very large sections of the application, the applicant shall submit a CD-R which contains the Sequence Listing or any other very large sections of the application. The applicant will deliver *two* copies of this CD.
- 2. The Sequence Listing and other text files must be formatted in plain ASCII text with line feeds, or as data files. Data files may be formatted as delimited records. The files included on the CD shall be sized and formatted to be readable by a PTO user using MS Word '97 on an IBM compatible desktop computer and the database files included on the CD shall be sized and formatted to be readable by a PTO user using MS Excel '97 on an IBM compatible desktop computer.

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3. It is crucial that all table information "line up" properly- applicant must add the appropriate spacing or formatting to make the tables accurate and legible.

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- 4. The Computer Readable Form required by 37 C.F.R. §1.821(e), and specified by 37 C.F.R. §1.824 is to be submitted by the applicant on a separate CD-R (or other medium as required by that rule section) from the CD-R containing the large tables or other application information.
- 5. A statement required under 37 C.F.R. §1.821(f) shall be submitted indicating that the nucleotide sequence information recorded on the CD-R as specified in paragraph 1 above is identical to that presented on the Computer Readable Form required by 37 C.F.R. §1.821(e) as set forth in paragraph 4.
- 6. Each CD-R will be encased in a flexible protective sleeve and the CD-R itself will be marked with an identification number in indelible ink.
- 7. Each CD-R will be individually described in the specification in a conspicuous manner, in a section near the beginning of the specification, referring to the identification number inscribed on the CD-Rs. The applicant will describe each file contained on each CD-R by the names, sizes, titles and nature of the content of the file. All future submitted or substitute CD-Rs will be described in this manner in the specification.
- 8. The remainder of the application is to be prepared in paper in accordance with the standards of 37 C.F.R. §1.52 and other relevant regulations

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9. Resubmission of the Sequence Listings for this application only will be on CD-Rs in accordance with the requirements of this decision.

10. The provisions of 37 CFR § 1.19 will not apply to any request for a copy (certified or uncertified) of the subject application-as-filed or application file. The Office of Public Records will specify the charge for any copies of the subject application requested by petitioner.

It is important that the applicant should carefully review the electronic files to ensure that essential subject matter that might be in table formatting is not lost when the file is presented in a compliant file format.

Restriction/Election Requirement

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-5 and 7-10, drawn to methods of identifying novel nucleic acid molecules, classified in Class 536, subclass 6.
- II. Claim 6, drawn to a method of identifying the effect of a gene knockout on a regulatory pathway, classified in Class 800, subclass 21.
- III. Claims 11-21, drawn to methods for extracting information on interactions between biological entities from natural-language text data, classified in Class 702, subclass 31.
- IV. Claims 22-32, drawn to a computer system for extracting information on biological entities from natural-language text data, classified in Class 364, subclass 528.01.

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Each of Groups I-III is directed to a separate and distinct invention. Group I is directed to methods of identifying novel nucleic acid molecules; Group II is directed to a method of identifying the effect of a gene knockout on a regulatory pathway, and Group III is directed to methods for extracting information on interactions between biological entities from natural-language text data. The methods as claimed are distinct both physically and functionally, require different process steps, reagents and parameters, and importantly produce different products. Consequently, these inventions have acquired a separate status in the art as a separate subject for inventive effect and are usually published-separately. The search-for each-of-the above inventions is not-co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of any one Group would not necessarily anticipate or make obvious any of the other groups.

The inventions of Groups III and IV are related as product and distinct process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the computer system for extracting information on biological entities of Group IV can be used in the process of the invention of Group III, i.e. for extracting information on interactions between biological entities. Alternatively, the system can also be used for extracting information on regulations between biological entities, wherein interaction is not involved in the regulation between biological entities.

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Because these inventions are independent/distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Note that a fully responsive communication will comprise a proper election of a group, as well as compliance with the sequence rules and the microfiche guidelines, as set forth above. Examination cannot proceed without a complete response.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be_directed_to_Patent Analyst_Tina_Plunkett whose_telephone_number_is (703)=305=3524, ... or to the Technical Center receptionist whose telephone number is (703) 308-0196.

S. "Joe" Zhou: sjz

December 27, 2000

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